DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 15, 2015

Gergen's Orthodontic Lab, Inc.
c/o Karen E. Warden, Ph.D.
BackRoads Consulting
P.O. Box 566
Chesterland, OH 44026

Re: K143591
Trade/Device Name: Dorsal Appliance
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral device for snoring and intraoral device for snoring and obstructive sleep apnea
Regulatory Class: II
Product Code: LRK
Dated: January 25, 2015
Received: January 28, 2015

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143591

Device Name
Dorsal Appliance

Indications for Use *(Describe)*
The Dorsal Appliance is intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 8 – 510(k) Summary

Date:	**17 December 2014**
Sponsor:	Gergen's Orthodontic Lab Inc. 1745 West Deer Valley Rd, Suite 112 Phoenix, AZ 85027 Phone: 623-879-6066 Fax: 623-879-6166
Contact Person:	Chris Morrison, Lab Manager
Proposed Trade Name	Dorsal Appliance
Common Name:	Anti-snoring appliance
Device Classification	Class II
Classification Name:	Device, Anti-Snoring
Regulation Number, Name:	872.5570, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Device Product Code:	LRK
Submission Purpose:	The Dorsal Appliance is a modification of the Acrylic Herbst Appliance.
Device Description:	The Dorsal Appliance is comprised of upper and lower customized acrylic splints for the treatment of mild to moderate sleep apnea. The upper splint comprises bilateral turnbuckle adjustment mechanisms. The device aims to improve the patient's air exchange thereby reducing snoring and apnea by increasing the pharyngeal space through anterior repositioning of the mandible.
Intended Use:	The Dorsal Appliance is intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older.
Materials:	Medical grade polymethylmethacrylate (acrylic splints) and stainless steel (adjustment screw mechanism)
Predicate Devices:	Primary: Acrylic Herbst Appliance (Gergen's, K113126) Reference: Dorsal Appliance (Dynaflex Inc., K103076)
Performance Data:	The materials and fabrication processes used in the manufacture of the subject device are identical to the materials and fabrication processes used in the manufacture of the predicate device. Because material biocompatibility was accepted for the predicate and because there are no differences in manufacturing which could affect biocompatibility, additional biocompatibility testing was not supplied in support of this clearance. Data regarding performance testing of the device material was provided. Because the identical material is used for both the subject and predicate devices, these performance results support the finding of substantial equivalence. The results included general properties (water solubility and absorption) and physical properties (tensile and flexural strength, and elastic modulus). Clinical testing of the subject device was not used in support of clearance. Per the *Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA*, a risk analysis was performed with respect to the subject device. The risks identified in the guidance (e.g., intraoral gingival, palatal, or dental soreness; TMJ Dysfunction Syndrome; obstruction of oral breathing and loosening or flaring of lower anterior teeth or general tooth movement) and those detected by the risk analysis were mitigated though the use of biocompatible materials identical to those used in the predicate and the use of appropriate labeling.

Technological Characteristics: The fundamental scientific technology of the Gergen's Orthodontic Dorsal Appliance is the same as the previously cleared device shown below, i.e., each of the design features is common to the predicate.

System:	Dorsal Appliance	Acrylic Herbst Appliance
Manufacturer:	**Gergen's Orthodontic**	**Gergen's Orthodontic**
510(k):	**Under review**	**K113126**
Intended use:	The reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA)	The reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA)
Target population:	Adults	Adults
Prescription use:	Prescription only	Prescription only
Basic Design:	Upper and lower splints having an adjustment mechanism	Upper and lower splints having an adjustment mechanism
Function:	To increase the patient's the pharyngeal space and improve air exchange thereby reduce snoring and apnea by anterior repositioning of the mandible	To increase the patient's the pharyngeal space and improve air exchange thereby reduce snoring and apnea by anterior repositioning of the mandible
Materials of manufacture:	Medical grade acrylic and stainless steel	Medical grade acrylic and stainless steel
Adjustability:	Yes, by prescribing dentist or physician	Yes, by prescribing dentist or physician
Adjustment mechanism:	Yes, turnbuckle	Yes, telescopic
Adjustable range:	5mm	5.5mm
Method of manufacture:	Patient-specific customized fabrication	Patient-specific customized fabrication
Sterility:	Non-sterile	Non-sterile

Conclusion:

From the chart above, the only differences between the subject device and the primary predicate is the type of advancement mechanism used and the adjustable range allowed by the devices. Although the advancement mechanism differs, the type used for the subject device is also used in other similar intra-oral devices such as the reference predicate device (Dorsal Appliance). Therefore, the difference in the type of advancement mechanism does not raise any new safety and effectiveness questions. The adjustable range of the primary predicate device is slightly higher than the subject device; however this range falls within the limits of other similar predicate devices.

In comparison to the predicate device, the Dorsal Appliance has

- the same intended use (as described above),
- technological characteristics which do not raise new questions of safety and effectiveness.

Therefore the Dorsal Appliance can be found substantially equivalent to the predicate device.